

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :
Christian MAYAUD :
Rule 53b Continuation of :
Serial No.: 09/121,596, Filed: July 24, 1998: Group Art Unit: 2166 :
Filed: August 30, 2001 : Examiner: S. Rimell :
For: PRESCRIPTION MANAGEMENT SYSTEM

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, DC 20231

Sir:

This Preliminary Amendment is being filed with a Rule 53b Continuation Application. Prior to examination on the merits, please amend the application as follows:

IN THE TITLE:

Please change the title of the above-referenced application to --A
COMPUTERIZED PRESCRIPTION SYSTEM FOR GATHERING AND
PRESENTING INFORMATION RELATING TO PHARMACEUTICALS--.

IN THE ABSTRACT:

Please cancel the Abstract and substitute therefor the Abstract set forth on a separate sheet herewith.

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ABSTRACT

A wirelessly deployable, electronic prescription creation system for physician use captures into a prescription a patient condition-objective of the prescribed treatment and provides for patient record assembly from source elements, with privacy controls for patient and doctor, adverse indication review and online access to comprehensive drug information including scientific literature. Extensions to novel multi-drug packages and dispensing devices, and an "intelligent network" remote data retrieval architecture as well as onscreen physician-to-pharmacy and physician-to-physician e-mail are also provided.--

IN THE DRAWINGS:

Please approve the proposed amendments to the drawings as shown in the attached Request for Approval of Drawing Amendment, comprising the proposed addition of new Figures 17-21.

IN THE SPECIFICATION:

Page 1, between the title and line 1, please insert the following:

--CROSS REFERENCE TO RELATED APPLICATIONS

This application is a Continuation of Application Serial No. 09/121,596 filed July 24, 1998, which is a Continuation of Application Serial No. 08/942,372, filed October 2, 1997 (now U.S. Patent No. 5,845,255), which is a Continuation of Application Serial No. 08/330,745, (now abandoned).--

Please replace the paragraph beginning at page 3, line 17 through page 4, line 5, with the following rewritten paragraph:

--As used herein, the term "drug formulary" refers to a list of preferred drugs contained in a drug benefits plan issued by a drugs benefit provider to a given patient. Drug formularies are specific to groups of patients and vary in content as between one drug benefit provider and another and one patient group and another. Drug formulary information is usually determinative of the cost-effectiveness of a prescription. Unwitting failure by a prescriber to follow formulary guidelines can impose unnecessary or unexpected cost burdens on the patient, or their benefits provider, and lead to poor patient compliance and aggravating and time-consuming disputes. The cost in dollars of non-compliance with drug formulary

guidelines to benefit-providing corporations, insurers, health maintenance organizations and government providers, for example MEDICAID and MEDICARE, can be enormous. The cost of poor patient compliance may ultimately increase the total cost of care by generating a more serious, expensive adverse health outcome (emergency room visit, or hospital admission or death).--

Please replace the paragraph beginning on page 11, line 7, with the following rewritten paragraph:

--More generally, the invention provides a computer-based professional product specification system for use by other professionals, in addition to physicians and, which can deliver substantial benefits to mobile users.--

Please replace the paragraph beginning on page 11, line 11, with the following rewritten paragraph:

--By associating a patient condition or problem with each drug prescribed, a treatment objective is both expressed and recorded, and the physician's intent is captured. The invention provides a user-friendly prescription management system which requires minimal data entry enabling many prescriptions to be created with an overall efficiency unobtainable by known automated systems and which can helpfully supplement the skills of the best of practitioners.--

Please replace the paragraph beginning on page 16, line 16, with the following rewritten paragraph:

-- **Figure 1** shows a system entry screen of a prescription creation system embodiment of the invention which system incorporates the screens of Figures 2-11;--

Please replace the paragraph beginning on page 17, line 13, with the following rewritten paragraph:

-- **Figure 15** illustrates a scheduled dosage drug package;--

Please replace the paragraph beginning on page 17, line 15, with the following rewritten paragraphs:

-- **Figure 16** is a schematic diagram of one way of connecting users of the prescription management system of Figures 1-14 with remote source databases across network to provide data and processing resources needed during operation of the prescription management system and useful inter alia for creation of a virtual patient record;

Figure 17 is a schematic block flow diagram showing a sequence of operating steps of the prescription creation system shown in Figures 1-11;

Figure 18 is a diagram similar to the diagram of Figure 17, showing a condition drive drug selection procedure;

Figure 19 is a diagram similar to the diagram of Figure 17, showing a drug selection evaluation procedure;

Figure 20 is a diagram similar to the diagram of Figure 17, showing a direct drug selection procedure; and

Figure 21 is a diagram similar to the diagram of Figure 17, showing a drug and condition list updating procedure.--

Please replace the paragraph beginning on page 19, line 11, with the following rewritten paragraph:

--Referring to Figures 1 to 14 of the drawings, the screens shown employ user-friendly data selection and data entry devices for capturing data such as are familiar to many computer users in Apple Corporation's Macintosh® (trademark) and Microsoft Corporation's Windows operating system, for example activatable buttons, pointers, scroll bars, icons, arrow key, drop-down menus, windows and other screen symbols designed for actuation by a pointing device, for example, a mouse or trackball. More preferably, for compact "pocket-book" computer applications, the pointing device is a pen or stylus.--

Please replace the paragraph beginning on page 28, line 25 through page 29, line 6, with the following rewritten paragraph:

--A still more preferred feature is to have user passwords which link each user with an individual profile or style sheet on the host computer facility representing the user's pattern of preferences so that the user-customization features of the system, which will be described more fully hereinafter, are readily available to the user independently of the particular interface device that happens to be employed for accessing the system.--

Please replace the paragraph beginning on page 33, line 6, with the following rewritten paragraph:

--A Doctor's Lists button 24 accesses a more or less complex library of patient condition and therapeutic drug lists. Preferably, the drug and condition lists are linked together to

associate a drug with one or more conditions for which it might be prescribed and, in most cases to provide the physician user with a conveniently displayed, concise selection of drugs for treating any particular condition. In a preferred feature of this invention, the system has a user-adaptive character and adapts itself to the user's habits and prescribing patterns so as to service the user more efficiently. To this end, the drug lists or the condition lists, or both, are system-generated and system modified with the use block 123 (Fig. 21) to reflect the prescribing frequency of particular drugs block 87 or the frequency of occurrence of particular conditions block 89. Thus, more frequently prescribed drugs or more frequently encountered conditions can be presented to the user physician in a more prominent manner or more immediate manner than those ones found by the system to be historically less common in the particular user prescribing environment. In this way the system becomes more valuable with use as the drug and condition lists develop into personalized lists featuring the user's preferences.--

Please replace the paragraph beginning on page 44, line 22 through page 45, line 5, with the following rewritten paragraph:

--Upon selecting **Prescribing** button 18 by clicking or pen contact, a Select Patient Screen 46, for example as shown in Figure 2, is displayed as a preliminary to prescription management functions. Referring to the patient selection screen of Figure 2, and the flow diagram of Figure 17, the name, age, gender, and social security numbers of patients who have authorized the user physician to treat them, or to access the system on their behalf, are listed under respective column header buttons, namely, **Name** button 26, **Age** button 28, **Gender** button 30 and **Social Security #** button 32.--

Please replace the paragraph beginning on page 45, line 20, with the following rewritten paragraph:

--In Select Patient Screen 46 **New Pt** button 36 activates a new patient bar to enter a new patient name, block 37 (Fig. 17), while a patient who has authorized the user physician to treat him, can be highlighted from a list of patients 47. The **Ok** button 39 accepts a highlighted patient selection and advances to the prescription management screen of Figure 3. **Cancel** button 38 returns to the system entry screen of Figure 1.--

Please replace the paragraph beginning on page 48, line 26 through page 49, line 18, with the following rewritten paragraph:

--Patient-directed control of the flow of their own data, a novel concept in medical or health care information systems, can be achieved by centrally inputting at the host computer facility patient-generated record-access specifications to determine which users, or user organizations or departments (for example clinics), can access what data during what period and what uses can be made of the data. Clearly, such specifications must not deleteriously restrict physicians in the execution of their professional missions. Such record-access specifications or profiles can be maintained at a remote database rather than the host computer facility. Thus, access to their records is controlled by patients and individuals and organizations can be given patient-defined, selective access or access based on a need to know, or a patient may block access to all data flow, if they wish. In emergencies, physicians may be able to override a patient security block, but such events are recorded so that any abuse can be monitored and action can be taken to discourage abusers.--

Please replace the paragraph beginning on page 51, line 20 through page 52, line 6, with the following rewritten paragraph:

--Referring to Figure 3, prescription creation screen 39 has a full array of user-activatable buttons enabling a physician to draw on powerful resources within the prescription management system as well as supporting resources in the host computer facility and associated data-retrieval network, as will shortly be described. Near the top of screen 39 is a patient features bar 40 below which a prescription features bar 42 coordinates all features necessary to review current therapy and order changes in treatment, or order new treatment, for the selected patient. A prescription history zone 43 extends across the middle of the screen, the lower screen portion contains a prescribing zone 44, and a screen title 45 appears at the top of the screen.--

Please replace the paragraph beginning on page 52, line 8, with the following rewritten paragraph:

--Patient features bar 40 comprises a **Select Patient** button 46, a selected patient indicator 48, in this case **Mary Harrington**, a patient **Problems** button 50 and a patient **Allergies** button 52. Beneath **Problems** button 50 are displayed Mary Harrington's currently active problems 51 or conditions, shown here as pharyngitis and bronchitis. Beneath **Allergies** button 52 are displayed Mary Harrington's known allergies. Pressing or otherwise activating **Problems** button 50 or **Allergies** button 52 accesses the remote databases for the patient's history and opens a window or screen listing problems or allergies from which a physician, or other professional user, can select new problems or allergies to add to Mary Harrington's

record, or delete ones that are no longer active. Optionally, system-provided problem or allergy libraries may be organized into multiple lists with button 50 or 52, respectively, opening a list selection box as a preliminary to displaying a selected problem or allergy list.--

Please replace the paragraph beginning on page 54, line 16, with the following rewritten paragraph:

--Prescribing zone 44, lower down prescription creation screen 39, allows a physician user to select and prescribe drugs block 45, (for example, using a routine such as shown in Figure 18 or Figure 19) and dosages, for the selected patient, in this case Mary Harrington, and to transmit the created prescription by activating the send Rx button 80, externally across a data network to other interested and authorized parties for prescription fulfillment, block 55, patient record updating, arrow 57, and the like. **Send Rx** button 80 can also output the prescription to print, block 59, or storage.--

Please replace the paragraph beginning on page 55, line 19 through page 56, line 1, with the following rewritten paragraph:

--The patient's drug-related allergies, or drug reactions, are brought up in possibly editable form (screen not shown) by activating an **Allergies** button 52 and may be automatically system updated, if desired by adding newly reported drug reactions and allergies, arrow 51. Desired personal or drug records relevant to possible allergies of this patient may be summoned from the host computer facility, which may in turn call on the remote database data-retrieval network block 41 (Fig. 17) for records or record elements.--

Please replace the paragraph beginning on page 56, line 14, with the following rewritten paragraph:

--A highlighted prior prescription can be automatically renewed by clicking or pushing an **Renew Rx** button 62. Typically, prescription creation screen 39 opens with the most recent prescription highlighted for possible renewal. Activating **Renew Rx** button 62 posts a highlighted prior prescription into prescribing zone 44 for automatic renewal, after editing, if desired. Renewal of any prior prescription can thus be effected in as few as two user steps by pressing **Renew Rx** 62 to post a highlighted previous prescription to prescribing zone 44 and completing a prescription in a single step from there. If desired option buttons such as **Renew and Send Last Prescription** or **Renew All Active Prescriptions** can be added.--

Please replace the paragraph beginning on page 60, line 1, with the following rewritten paragraph:

--Implementation of the invention is expected dramatically to reduce the overall cost of prescriptions and this saving has been estimated to be from 20 to 40 percent of total prescription costs. Savings will accrue initially to the drug benefit management companies who reimburse the direct costs of most prescriptions, but can be expected eventually to be passed to corporations and consumers by way of lower drug benefit rates. Such savings realized on a national scale would amount to many billions of dollars and provide reimbursement of system costs to system users . In the early 1990's, the cost of prescription drug benefits is one of the fastest rising components of all health care costs.--

Please replace the paragraph beginning on page 60, line 5, with the following rewritten paragraph:

--Organizations participating in outcome studies, for example, health maintenance organizations, insurance companies, hospitals, physician alliances and the like, may pool their data but may not wish to reveal certain proprietary data. By employing data access control methods for accessing such organizational data, such as the methods described in detail herein for controlling access to data to which patients have rights, the system of this invention can enable organizations to control what data they release.--

Please replace the paragraph beginning on page 64, line 22, with the following rewritten paragraph:

--Continuous post-market-introduction monitoring of a drug in relation to the treatment of conditions is possible, and an end-to-end solution to the problem of managing unanticipated problems arising with new drugs can be provided: the system provides a vehicle for collecting relevant data; parameters for evaluating and a means for analysis of that data; and a means for disseminating alerts and advisories regarding newly discovered problems. The same vehicle is used for all three steps.--

Please replace the paragraph beginning on page 85, line 11, with the following rewritten paragraph:

--A further valuable feature of the novel prescription management system described herein is an ability to review a completed prescription for contraindications, or relative contraindications, such as patient allergies to the prescribed drug and such as possible drug-

to-drug interactions with other drugs the patient has previously been prescribed. Contraindications may be clear-cut, for example, penicillin must not be selected for penicillin-allergic patients, whereas relative contraindications are less decisive and may be overridden by the prescriber in appropriate circumstances, for example an NSAID (non-steroidal anti-inflammatory drug) may be a preferred choice, in the prescriber's judgment for a patient with peptic ulcer disease, in spite of the attendant risks.--

Please replace the paragraph beginning on page 86, line 19 through page 87, line 6, with the following rewritten paragraph:

--An allergies review can be conducted by checking system-stored known allergies of patient **Mary Harrington** against known pharmacokinetics and pharmacodynamics of the newly prescribed drug, entered in prescribing zone 44, for any of those allergies. Mary Harrington's allergy information is preferably an adjunct to her patient record and is downloaded to the user device from the host computer facility when Mary Harrington is selected from the patient selection screen of Figure 2. Drug allergenic proclivities are also downloaded from one or another remote database employing the host computer facility, under supervision of the inventive prescription management system, but preferably at a later point in the procedure, such as when a particular drug is selected for posting to prescribing zone 44.--

Please replace the paragraph beginning on page 87, line 8, with the following rewritten paragraph:

--Alternatively, the requisite information can be downloaded when the allergy review is conducted. Such allergy screening can alternatively be effected when a new drug is posted to **Drug** field 88. Either way, a positive system finding, indicating a risk of allergic reaction to the newly selected drug can activate a visual indicator or warning, for example, **Allergies** button 52 may blink and, if desired, an audible warning may sound alerting the physician to reconsider their selection. Alternatively, or additionally, an alert screen can tell the physician of an allergy if an attempt is made to prescribe an offending drug. Such alerts can be used to notify the physician of drug interactions, can provide adverse treatment warnings or can alert them to non-compliance with formulary recommendations, for example, to the use of an unnecessarily expensive drug, and may be accompanied by suggestions for more appropriate alternative therapies.--

Please replace the paragraph beginning on page 87, line 25 through page 88, line 7, with the following rewritten paragraph:

--Equivalent procedures can alert to possible drug interactions and contraindications, referring to the patient's prescription history for possible active or recently expired prescriptions that may interact with a newly prescribed drug, and for other patient data relevant to the drug's behavior in that patient. Alternatively, such a review for possible undesired aspects of the drug's performance on the patient is made upon activating **Send Rx** button 80.--

Please replace the paragraph beginning on page 91, line 21 through page 92, line 11, with the following rewritten paragraph:

--Novel drug selection methods pursuant to the invention will now be described with reference to Figures 4 to 11. The condition list selection screen shown in Figure 4 appears upon activation of **Condition** field 86 in the prescription management screen of Figure 3, to enable a prescriber to approach selection of a treatment drug by first specifying a diagnosed condition. Alternatively, a drug may be directly specified by drug name (Fig. 20) by activating **Drug** field 88, as will be described in connection with Figure 9, after which the prescriber selects a condition to specify the purpose of the therapy block 111. Such condition or drug selection screens can be opened similar condition or drug buttons in any other relevant screen or application, for instance in a patient encounter screen where the drug selection routines now to be described with reference to Figures 4 to 11 can be used to assist a physician to select or review treatment objectives in a computer-assisted patient encounter.--

Please replace the paragraph beginning on page 99, line 21 through page 100, line 2, with the following rewritten paragraph:

--Where formulary drugs are professionally acceptable to the physician and of equivalent therapeutic effect to non-formulary drugs, failure to use them is clearly undesirable. This problem is overcome by the present invention. If the physician is satisfied with the formulary drugs offered by the prescription management system of this embodiment, any one formulary drug may be selected and automatically posted to the novel prescription described herein as will be described.--

Please replace the paragraph beginning on page 105, line 4, with the following rewritten paragraph:

-- Referring to Figure 9, an alternative direct drug-specification pathway commences, reading from left to right, with selection of drug list 115 **Rx by Therapeutic Class**. From a list of perhaps fifty to one hundred drug categories 119 which appears in the next right hand column, the prescriber has picked Diuretics, generating an even longer list of diuretic drugs 121 from which the prescriber has picked Dyazide (trademark, Smith Kline Beecham). The system now calls for entry of a condition block 111, in this case "hypertension". The extent of the lists of drug categories 119 and diuretics 121, again illustrates the bewildering array of drug selections with which a prescriber is confronted. An otherwise uncertain or overly conservative decision-making process can be rendered efficient, reliable and manageable by a prescription management system according to the invention.--

Please replace the paragraph beginning on page 108, line 26 to page 109, line 20, with the following rewritten paragraph:

--A powerful optional feature of the invention is shown in exemplary fashion by the drug evaluation screen depicted in Figure 11. After a physician selects a drug block 121 from one of the screens of Figures 7 to 10, the system can optionally scan a drug preference database of preferred drug treatments block 71 and the selected patient's history record for an evaluation of the merits of the selected drug in treating the condition in general and for this selected patient. The drug preference database may be remote and may be maintained, for example, by a managed care organization, HMO, or prescription benefits

management company. As the Figure 11 example shows (which example employs different condition and drug selections from those used in Figures 6 and 7) one possible result of the database scan may be an on-screen report with an alert message, in header 126 advising the physician that the selected drug is "Not a first line drug" for treating the selected condition. As a helpful suggestion to the physician the system can also offer alternative drugs, from listings in the drug preference database, as being more meritorious for the treatment of the condition in question (pursuant to the maintaining benefit company's standards or, preferably, to objective literature reports).--

Please replace the paragraph beginning on page 109, line 22 to page 110, line 5, with the following rewritten paragraph:

--To this end, the drug selection evaluation block 169 screen of Figure 11 comprises an explanatory box 128 elucidating header 126; an alternative drug selection menu 130; and at the bottom of the screen, three action buttons; for example, Tx Guidelines 132 to access treatment information about the alternative drug highlighted in menu 130; a confirm button 134 to post the physician's original drug selection, in this case "Cefixime" and to return to prescription creation screen 39; and a cancel button 136 which returns the user to the drug-selection of Figure 7.--

Please replace the paragraph beginning on page 113, line 5, with the following rewritten paragraph:

--The system of the invention can provide a novel approach to drug formulary management whereby prescriber-centric formularies can be established. By means of the

system, drug formulary guidelines effectively adapt to the user's prescribing patterns or preferences can be followed effortlessly by the prescriber. This desirable prescriber-centricity can be obtained by giving priority to the prescriber's personal or custom lists or, better still if they are a subset of these, to the patient's history lists, and system-identifying patient-formulary preferences on those lists for easy final picking by the prescriber. Where the prescriber is selecting a drug providing effective therapy for a just-specified condition, the above procedure may often clearly identify a single drug meeting all requirements or may result in a short list of a very small number of drugs for final selection. Where no drug is listed as meeting all requirements, the system may so alert the user and suggest formulary drugs not on the doctor-specific lists or ask the user whether they wish to review appropriate non-formulary drugs from their personal or custom lists.--

Please replace the paragraph beginning on page 132, line 14, with the following rewritten paragraph:

--Communication between host computer facility 206 and remote databases 210 will usually be via wire lines such as telephone, or local or wide area network communication via copper line, or optical fiber, or any other suitable communication medium. Clearly, host computer facility 206 can access any remote third party database with which appropriate arrangements have been made, or can be made on line, and some possible source databases for patient records components are labeled as "HMO's 210A, Hospitals 210B, Insurance Co. 210C, Drug Benefit Co. 210D, Pharmacies 210E, Labs 210F, and Independent Physicians 210G". Drug information may be additionally sourced from

pharmaceutical companies' research centers, reference libraries, or publishers and the like.--

Please replace the paragraph beginning on page 137, line 21, with the following rewritten paragraph:

--The foregoing description has emphasized an approach to therapy prescribing which records an association between a therapeutic agent (drug) and a condition or problem targeted for resolution or amelioration by the prescribed therapeutic agent. Significant benefits derive from organizing known therapeutic agents according to conditions for which they are known to be effective, and emphasis has been placed herein on a drug selection and specification which begins with selection of a problem or condition to be treated, because this is believed to be an appealing and beneficial approach in many circumstances. Frequently however, the physician may know exactly what drug they wish to prescribe, in which case they can prescribe via direct drug selection block 67 by proceeding to a direct drug entry screen, and then specifying the condition targeted by the prescribed treatment when the system prompts entry of the condition block 111.--

IN THE CLAIMS:

Please cancel claims 1-69.

Please add the following new claims 70-91 as follows:

-- 70. A prescription generated by a computer-implemented prescription creation system having a program stored on a computer-readable medium, the system being for use by a prescriber to create an electronic prescription prescribing a drug to treat a

condition exhibited by a patient at a point-of-care, said electronic prescription comprising a patient identifier, at least one prescribed drug and at least one drug quantifier for the prescribed drug and being usable by a pharmacist to dispense the prescribed drug or drugs, said prescription creation system comprising:

a) a prescription creation screen having prescriber-operable data capture devices including:

- i) a patient identifier data capture device for capturing patient-identifying data;
- ii) a prescribed drug data capture device for capturing prescribed drug identification data;
- iii) at least one drug quantifier capture device for capturing drug quantification data;
- iv) a patient condition data capture device to capture patient condition data regarding said patient condition exhibited by said patient whereby said electronic prescription further comprises said patient condition data; and

b) a library of prescribable drug data accessible by one or more of said data capture devices from said prescription management screen to display multiple prescribable drugs;

c) a prescription output screen device to output a completed prescription; and

d) a printer to print the completed prescription;

wherein the completed prescription includes the patient condition and identification and quantification data regarding a drug prescribed by the prescriber user for treatment of the patient condition, the patient condition and drug data being captured into the prescription by the data capture devices.--

-- 71. A prescription according to claim 70 having at least one preferred usage data display including a personal-preference drug-selection list for each system user wherein

the system tracks preferred data usage by each system user and updates said preferred usage data displays automatically.--

-- 72. A prescription according to claim 71 wherein at least one said preferred usage data display comprises a personal-preference condition-selection list for each system user accessible from the prescription creation system during prescription creation.--

-- 73. A prescription according to claim 70 further comprising a patient history record for display, said patient history record listing electronically available prior prescription data including a prescribed drug and a condition treatment objective for each prescribed drug.--

-- 74. A prescription according to claim 73 comprising a patient condition list for selection of a patient condition for posting to said prescription, said patient condition list comprising patient conditions listed in said patient history record.--

-- 75. A prescription according to claim 70 comprising a source-oriented data-retrieval subsystem, said data retrieval subsystem being connectable to access at least one data-retrieval network to retrieve source prescribing information and patient-related data to the point-of-care from at least one remote source database. --

-- 76. A prescription according to claim 75 wherein said patient-related data comprises allergy or drug interaction information regarding the patient or comprises patient drug formulary changes.--

-- 77. A prescription according to claim 73 wherein said patient history record is a contemporaneous record dynamically assembled from multiple source record elements retrieved from multiple heterogeneous remote databases.--

-- 78. A prescription according to claim 77 implemented on a user interface device configured for networked digital communication with a host computer facility, wherein said patient history record is retrieved in the form of complementary record elements from multiple remote databases by said host computer facility.--

-- 79. A prescription according to claim 70 wherein said drugs in said drug list are classified into groups according to patient conditions for which said drugs have efficacy and said prescription creation system further comprises a patient-condition specification procedure for selecting said condition from groups of possible conditions and an onscreen drug selection procedure for selecting said prescribed drug from said library.--

-- 80. A prescription according to claim 70 wherein said patient has a drugs benefit provider, said drugs benefit provider issuing a prescription benefit plan including a drug formulary for said patient listing at least one drug preferred by said drugs benefit provider for treatment of said condition, and wherein the system further comprises:

a drug formulary display device identifying at least one of said displayed multiple drugs as a patient's drug formulary preference for treatment of said condition, to enable selection by said prescriber of a benefit plan recommended drug;

whereby the patient's drug formulary preference for treatment of said condition is system-presented to the prescriber prior to completion of the prescription and wherein said patient drug formulary data comprises a condition-driven formulary drug list, and a condition-driven nonformulary drug list, said drug lists being changeable according to the patient selected to identify drugs in the selected patient's drug formulary.--

-- 81. A prescription according to claim 70 including means to access remote source databases containing said drug formulary information and provided by the selected patient's prescription benefits management company whereby relevant patient formulary drugs are indicated to said user on screen.--

-- 82. A prescription according to claim 70 including information regarding prescribability of a drug pursuant to formulary guidelines, said information being formulary-qualified according to said patient condition.--

-- 83. A prescription according to claim 82 comprising a user data access auditor to log information as to the time, date and identity of third party access to said user history data, to provide a user data access audit trail.--

-- 84. A prescription according to claim 70 comprising a prescription expiration routine including dosing, amount and expiration drug quantifiers and comprising system calculation of a relationship between said drug quantifiers.--

-- 85. A prescription according to claim 70 comprising organization-generated source data retrievable for display in said prescription-creation system from at least one remote database, an organization-directed data-access control subsystem including data-access control specification means enabling an organization to authorize selective third party access to said organization-generated source data and comprising data access control means whereby only an authorized third party can access said organization-generated source data.--

-- 86. A prescription according to claim 70 wherein said condition list comprises at least five conditions, and said drug list comprises at least five drugs.--

-- 87. A prescription according to claim 70 wherein said drug information comprises associated condition information and dosage information for at least about fifty percent of all prescribable FDA-approved drugs.--

-- 88. A prescription according to claim 70 comprising output means to output a newly created electronic prescription additionally to local storage to remote storage or to remote file transfer as an electronic prescription, the system providing all said output options.--

-- 89. A prescription according to claim 70 comprising means for transmitting said electronic prescription across a network for fulfillment by a specified pharmacy.--

-- 90. A prescription according to claim 88 comprising a printed dosage schedule output for said patient.--

-- 91. A prescription according to claim 70 wherein said patient has a drugs benefit provider, said drugs benefit provider issuing a prescription benefit plan including a drug formulary for said patient listing at least one drug preferred by said drugs benefit provider for treatment of said condition, and wherein the system further comprises:

d) a drug formulary display device identifying at least one of said displayed multiple drugs as a patient's drug formulary preference for treatment of said condition, to enable selection by said prescriber of a benefit plan recommended drug;

whereby the patient's drug formulary preference for treatment of said condition is system-presented to the prescriber prior to completion of the prescription.--

REMARKS

This Preliminary Amendment is being filed concurrently with a Rule 53b Continuation Application. Entry of this Preliminary Amendment prior to examination on the merits is respectfully requested.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

MCDERMOTT, WILL & EMERY



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The following paragraph has been inserted on page 1, between the title and line 1:

--CROSS REFERENCE TO RELATED APPLICATIONS

This application is a Continuation of Application Serial No. 09/121,596 filed July 24, 1998, which is a Continuation of Application Serial No. 08/942,372, filed October 2, 1997 (now U.S. Patent No. 5,845,255), which is a Continuation of Application Serial No. 08/330,745, (now abandoned).--

The paragraph beginning at page 3, line 17 through page 4, line 5, has been amended as follows:

As used herein, the term "drug formulary" refers to a list of preferred drugs contained in a drug benefits plan issued by a drugs benefit provider to a given patient. Drug formularies are specific to groups of patients and vary in content as between one drug benefit provider and another and one patient group and another. Drug formulary information is usually determinative of the cost-effectiveness of a prescription. Unwitting failure by a prescriber to follow formulary guidelines can impose unnecessary or unexpected cost burdens on the patient, or their benefits provider, and lead to poor patient compliance and aggravating and time-consuming disputes. The cost in dollars of non-compliance with drug formulary guidelines to benefit-providing corporations, insurers, health maintenance organizations and government providers, for example MEDICAID and MEDICARE, can be enormous. The cost of poor patient compliance may ultimately increase the total cost of care by generating

a more serious, expensive adverse health outcome (emergency room visit, or hospital admission or death).

The paragraph beginning on page 11, line 7, has been amended as follows:

More generally, the invention provides a computer-based professional product specification system for use by other professionals, in addition to physicians and, which can deliver substantial benefits to mobile[,] users [who may be computer-inexperienced].

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Figure 17 is a schematic block flow diagram showing a sequence of operating steps of the prescription creation system shown in Figures 1-11;

Figure 18 is a diagram similar to the diagram of Figure 17, showing a condition drive drug selection procedure;

Figure 19 is a diagram similar to the diagram of Figure 17, showing a drug selection evaluation procedure;

Figure 20 is a diagram similar to the diagram of Figure 17, showing a direct drug selection procedure; and

Figure 21 is a diagram similar to the diagram of Figure 17, showing a drug and condition list updating procedure.

The paragraph beginning on page 19, line 11, has been amended as follows:

Referring to Figures 1 to 14 of the drawings, the screens shown employ user-friendly data selection and data entry devices for capturing data such as are familiar to many computer users in Apple Corporation's Macintosh® (trademark) and Microsoft Corporation's Windows operating system, for example activatable buttons, pointers, scroll bars, icons, arrow key, drop-down menus, windows and other screen symbols designed for actuation by

a pointing device, for example, a mouse or trackball. More preferably, for compact "pocket-book" computer applications, the pointing device is a pen or stylus.

The paragraph beginning on page 28, line 25 through page 29, line 6, has been amended as follows:

A still more preferred feature is to have user passwords which link each user with an individual profile or style sheet on the host computer facility representing the user's [patterns] pattern of preferences so that the user-customization features of the system, which will be described more fully hereinafter, are readily available to the user independently of the particular interface device that happens to be employed for accessing the system.

The paragraph beginning on page 33, line 6, has been amended as follows:

A Doctor's Lists button 24 accesses a more or less complex [display] library of patient condition and therapeutic drug lists. Preferably, the drug and condition lists are linked together to associate a drug with one or more conditions for which it might be prescribed and, in most cases to provide the physician user with a conveniently displayed, concise selection of drugs for treating any particular condition. In a preferred feature of this invention, the system has a user-adaptive character and adapts itself to the user's habits and prescribing patterns so as to service the user more efficiently. To this end, the drug lists or the condition lists, or both, are system-generated and system modified with the use block 123 (Fig. 21) to reflect the prescribing frequency of particular drugs block 87 or the frequency of occurrence of particular conditions block 89. Thus, more frequently prescribed drugs or more frequently encountered conditions can be presented to the user physician in a

more prominent manner or more immediate manner than those ones found by the system to be historically less common in the particular user prescribing environment. In this way the system becomes more valuable with use as the drug and condition lists develop into personalized lists featuring the user's preferences.

The paragraph beginning on page 44, line 22 through page 45, line 5, has been amended as follows:

Upon selecting **Prescribing** button 18 by clicking or pen contact, a [patient selection screen] Select Patient Screen 46, for example as shown in Figure 2, is displayed as a preliminary to prescription management functions. Referring to the patient selection screen of Figure 2, and the flow diagram of Figure 17, the name, age, gender, and social security numbers of patients who have authorized the user physician to treat them, or to access the system on their behalf, are listed under respective column header buttons, namely, **Name** button 26, **Age** button 28, **Gender** button 30 and **Social Security #** button 32.

The paragraph beginning on page 45, line 20, has been amended as follows:

In Select Patient Screen 46 **New Pt** button 36 activates a new patient bar to enter a new patient name, block 37 (Fig. 17), while [the] a patient who has authorized the user physician to treat him, can be highlighted from a list of patients 47. The **Ok** button 39 accepts a highlighted patient selection and advances to the prescription management screen of Figure 3. **Cancel** button 38 returns to the system entry screen of Figure 1.

The paragraph beginning on page 48, line 26 through page 49, line 18, has been amended as follows:

Patient-directed control of the flow of their own data, a novel concept in medical or health care information systems, can be achieved by centrally inputting at the [or a] host computer facility patient-generated record-access specifications to determine which users, or user organizations or departments (for example clinics), can access what data during what period and what uses can be made of the data. Clearly, such specifications must not deleteriously restrict physicians in the execution of their professional missions. Such record-access specifications or profiles can be maintained at a remote database rather than the host computer facility. Thus, access to their records is controlled by patients and individuals and organizations can be given patient-defined, selective access or access based on a need to know, or a patient may block access to all data flow, if they wish. In emergencies, physicians may be able to override a patient security block, but such events are recorded so that any abuse can be monitored and action can be taken to discourage abusers.

The paragraph beginning on page 51, line 20 through page 52, line 6, has been amended as follows:

Referring to Figure 3, prescription creation screen 39 has a full array of user-activatable buttons enabling a physician to draw on powerful resources within the prescription management system [and] as well as supporting [it] resources in the host computer facility and associated data-retrieval network, as will shortly be described. Near the top of screen 39 is a patient features bar 40 below which a prescription features bar 42 coordinates all features necessary to review current therapy and order changes in treatment, or order new

treatment, for the selected patient. A prescription history zone 43 extends across the middle of the screen, the lower screen portion contains a prescribing zone 44, and a screen title 45 appears at the top of the screen.

The paragraph beginning on page 52, line 8, has been amended as follows:

Patient features bar 40 comprises a **Select Patient** button 46, a selected patient indicator 48, in this case **Mary Harrington**, a patient **Problems** button 50 and a patient **Allergies** button 52. Beneath **Problems** button 50 are displayed Mary Harrington's currently active problems 51 or conditions, shown here as pharyngitis and bronchitis. Beneath **Allergies** button 52 are displayed Mary Harrington's known allergies. Pressing or otherwise activating **Problems** button 50 or **Allergies** button [52,] 52 accesses the remote databases for the patient's history and opens a window or screen listing problems or allergies from which a physician, or other professional user, can select new problems or allergies to add to Mary Harrington's record, or delete ones that are no longer active. Optionally, system-provided problem or allergy libraries may be organized into multiple lists with button 50 or 52, respectively, opening a list selection box as a preliminary to displaying a selected problem or allergy list.

The paragraph beginning on page 54, line 16, has been amended as follows:

Prescribing zone 44, lower down prescription creation screen 39, allows a physician user to select and prescribe drugs block 45, (for example, using a routine such as shown in Figure 18 or Figure 19) and dosages, for the selected patient, in this case Mary Harrington, and to transmit the created prescription by activating the send Rx button 80, externally across a data network to other interested and authorized parties for prescription fulfillment, block 55,

patient record updating, arrow 57, and the like. Send Rx button 80 can also output the prescription to print, block 59, or storage.

The paragraph beginning on page 55, line 19 through page 56, line 1, has been amended as follows:

The patient's drug-related allergies, or drug reactions, are brought up in possibly editable form (screen not shown) by activating an **Allergies** button [48] 52 and may be automatically system updated, if desired by adding newly reported drug reactions and allergies, arrow 51. Desired personal or drug records relevant to possible allergies of this patient may be summoned from the host computer facility, which may in turn call on the remote database data-retrieval network block 41 (Fig. 17) for records or record elements.

The paragraph beginning on page 56, line 14, has been amended as follows:

A highlighted prior prescription can be automatically renewed by clicking or pushing an **Renew Rx** button 62. Typically, prescription creation screen 39 opens with the most recent prescription highlighted for possible renewal. Activating **Renew Rx** button 62 posts a highlighted prior prescription into prescribing zone 44 for automatic renewal, after editing, if desired. Renewal of any prior prescription can thus be effected in as few[,] as two user steps by pressing **Renew Rx** 62 to post a highlighted previous prescription to prescribing zone 44 and [a single further action to complete] completing a prescription in a single step from there. If desired option buttons such as **Renew and Send Last Prescription** or **Renew All Active Prescriptions** can be added.

The paragraph beginning on page 60, line 1, has been amended as follows:

Implementation of the invention is expected dramatically to reduce the overall cost of prescriptions and this saving has been estimated to be from 20 to 40 percent of total prescription costs. Savings will accrue initially to the drug benefit management companies who reimburse the direct costs of most prescriptions, but can be expected eventually to be passed to corporations and consumers by way of lower drug benefit rates. Such savings realized on a national scale would amount to many billions of dollars and provide [an avenue of reimbursement for system proprietors] reimbursement of system costs to system users . In the early 1990's, the cost of prescription drug benefits is one of the fastest rising components of all health care costs.

The paragraph beginning on page 60, line 5, has been amended as follows:

Organizations participating in outcome studies, for example, health maintenance organizations, insurance companies, hospitals, physician alliances and the like, [and] may pool their data but may not wish to reveal certain proprietary data. By employing data access control methods for accessing such organizational data, such as the methods described in detail herein for controlling access to [patient's] data to which patients have rights, the system of this invention can enable organizations to control what data they release.

The paragraph beginning on page 64, line 22, has been amended as follows:

Continuous post-market-introduction monitoring of a drug in relation to the treatment of conditions is possible, and an end-to-end solution to the problem of managing unanticipated

problems arising with new drugs can be provided: the system provides a vehicle [data] for collecting relevant data; parameters for evaluating and a means for analysis of that data; and a means for disseminating alerts and advisories regarding newly discovered problems. The same vehicle is used for all three steps.

The paragraph beginning on page 85, line 11, has been amended as follows:

A further valuable feature of the novel prescription management system described herein is an ability to review a completed prescription for contraindications, or relative contraindications, such as patient allergies to the prescribed drug and such as possible drug-to-drug interactions with other drugs the patient has previously been prescribed. Contraindications may be clear-cut, for example, penicillin must not be selected for penicillin-allergic patients, whereas relative contraindications are less decisive and may be overridden by the prescriber in appropriate circumstances, for example an NSAID (non-steroidal anti-inflammatory drug) may be a preferred choice, in the prescriber's judgment for a patient with peptic ulcer disease, in spite of the attendant [risk of ??] risks.

The paragraph beginning on page 86, line 19 through page 87, line 6, has been amended as follows:

An allergies review can be conducted by checking system-stored known allergies of patient **Mary Harrington** against known pharmacokinetics and pharmacodynamics of the newly prescribed drug, entered in prescribing zone 44, for any of those allergies. Mary Harrington's allergy information is preferably an adjunct to her patient record and is downloaded to the user device from the host computer facility when Mary Harrington is

selected from the patient selection screen of Figure 2. Drug allergenic proclivities are also downloaded from one or another remote database employing the host computer facility, under supervision of the inventive prescription management system, but preferably at a later point in the procedure, such as when a particular drug is selected for posting to prescribing zone 44.

The paragraph beginning on page 87, line 8, has been amended as follows:

Alternatively, the requisite information can be downloaded when the allergy review is conducted. Such allergy screening can alternatively be effected when a new drug is posted to **Drug** field 88. Either way, a positive system finding, indicating a risk of allergic reaction to the newly selected drug can activate a visual indicator or warning, for example, **Allergies** button 52 may blink and, if desired, an audible warning may sound alerting they physician to reconsider their selection. Alternatively, or additionally, an alert screen can tell the physician of an allergy if an attempt is made to prescribe an offending drug. Such alerts can be used to notify the physician of drug interactions, can provide adverse treatment warnings or can alert them to non-compliance with formulary recommendations, for example, to the use of an unnecessarily expensive drug, and may be accompanied by suggestions for more appropriate alternative therapies.

The paragraph beginning on page 87, line 25 through page 88, line 7, has been amended as follows:

Equivalent procedures can alert to possible drug interactions and contraindications, referring to the patient's prescription history for possible active or recently expired prescriptions that

may interact with a newly prescribed drug, and for other patient data relevant to the drug's behavior in that patient. Alternatively, [the] such a review for possible undesired aspects of the drug's performance on the patient is made upon activating **Send Rx** button 80.

The paragraph beginning on page 91, line 21 through page 92, line 11, has been amended as follows:

Novel drug selection methods pursuant to the invention will now be described with reference to Figures 4 to 11. The condition list selection screen shown in Figure 4 appears upon activation of **Condition** field 86 in the prescription management screen of Figure 3, to enable a prescriber to approach selection of a treatment drug by first specifying a diagnosed condition. Alternatively, a drug may be directly specified by drug name (Fig. 20) by activating **Drug** field 88, as will be described in connection with Figure 9, after which the prescriber selects a condition to specify the purpose of the therapy block 111. Such condition or drug selection screens can be opened similar condition or drug buttons in any other relevant screen or application, for instance in a patient encounter screen where the drug selection routines now to be described with reference to Figures 4 to 11 can be used to assist a physician to select or review treatment objectives in a computer-assisted patient encounter.

Please replace the paragraph beginning on page 99, line 21 through page 100, line 2, has been amended as follows:

Where formulary drugs are professionally acceptable to the physician and of equivalent therapeutic effect to non-formulary drugs, failure to use them is clearly undesirable. This

problem is overcome by the present invention. If the physician is satisfied with the formulary drugs offered by the prescription management system of this embodiment, [anyone] any one formulary drug may be selected and automatically posted to the novel prescription described herein as will be described.

The paragraph beginning on page 105, line 4, has been amended as follows:

Referring to Figure 9, an alternative direct drug-specification pathway commences, reading from left to right, with selection of drug list 115 **Rx by Therapeutic Class**. From a list of perhaps fifty to one hundred drug categories 119 which appears in the next right hand column, the prescriber has picked Diuretics, generating an even longer list of diuretic drugs 121 from which the prescriber has picked Dyazide (trademark, Smith Kline Beecham). The system now calls for entry of a condition block 111, in this case "hypertension". The extent of the lists of drug categories 119 and diuretics 121, again illustrates the bewildering array of drug selections with which a prescriber is confronted. An otherwise uncertain or overly conservative decision-making process can be rendered efficient, reliable and manageable by a prescription management system according to the invention.

The paragraph beginning on page 108, line 26 to page 109, line 20, has been amended as follows:

A powerful optional feature of the invention is shown in exemplary fashion by the drug evaluation screen depicted in Figure 11. After a physician selects a drug block 121 from one of the screens of Figures 7 to 10, the system can optionally scan a drug preference

database of preferred drug treatments block 71 and the selected patient's history record for an evaluation of the merits of the selected drug in treating the condition in general and for this selected patient. The drug preference database may be remote and may be maintained, for example, by a managed care organization, HMO, or prescription benefits management company. As the Figure 11 example shows (which example employs different condition and drug selections from those used in Figures 6 and 7) one possible result of the database scan may be an on-screen report with an alert message, in header 126 advising the physician that the selected drug is "Not a first line drug" for treating the selected condition. As a helpful suggestion to the physician the system can also offer alternative drugs, from listings in the drug preference database, as being more meritorious for the treatment of the condition in question (pursuant to the maintaining benefit company's standards or, preferably, to objective literature reports).

The paragraph beginning on page 109, line 22 to page 110, line 5, has been amended as follows:

To this end, the drug selection evaluation block 169 screen of Figure 11 comprises an explanatory box 128 elucidating header 126; an alternative drug selection menu 130; and at the bottom of the screen, three action buttons; for example, Tx Guidelines 132 to access treatment information about the alternative drug highlighted in menu 130; a confirm button 134 to post the physician's original drug selection, in this case "Cefixime" and to return to prescription creation screen 39; and a cancel button 136 which returns the user to the drug-selection of Figure 7.

The paragraph beginning on page 113, line 5, has been amended as follows:

The system of the invention can provide a novel approach to drug formulary management whereby prescriber-centric formularies can be established. By means of the system, drug formulary guidelines effectively adapt to the user's prescribing patterns or preferences can be followed effortlessly by the prescriber. This desirable prescriber-centricity can be obtained by giving priority to the prescriber's personal or custom lists or, better still if they are a subset of these, to the patient's history lists, and system-identifying patient-formulary preferences on those lists for easy final picking by the prescriber. Where the prescriber is selecting a drug providing effective therapy for a just-specified condition, the above procedure may often clearly identify a single drug meeting all requirements or may result in a short list of a very small number of drugs for final selection. Where no drug is listed as meeting all requirements, the system may so alert the user and suggest formulary drugs not on the doctor-specific lists or ask the user whether they wish to review appropriate non-formulary drugs from their personal or custom lists.

The paragraph beginning on page 132, line 14, has been amended as follows:

Communication between host computer facility 206 and remote databases 210 will usually be via wire lines such as telephone, or local or wide area network communication via copper line, or optical fiber, or any other suitable communication medium. Clearly, host computer facility 206 can access any remote third party database with which appropriate arrangements have been made, or can be made on line, and some possible source databases for patient records components are labeled as ["HMO's, Hospitals Insurance, Drug Benefit Cos, Pharmacies, Labs and Independent Physicians"] "HMO's

210A, Hospitals 210B, Insurance Co. 210C, Drug Benefit Co. 210D, Pharmacies 210E, Labs 210F, and Independent Physicians 210G". Drug information may be additionally sourced from pharmaceutical companies' research centers, reference libraries, or publishers and the like.

The paragraph beginning on page 137, line 21, has been amended as follows:

The foregoing description has emphasized an approach to therapy prescribing which records an association between a therapeutic agent (drug) and a condition or problem targeted for resolution or amelioration by the prescribed therapeutic agent. Significant benefits derive from organizing known therapeutic agents according to conditions for which they are known to be effective, and emphasis has been placed herein on a drug selection and specification which begins with selection of a problem or condition to be treated, because this is believed to be an appealing and beneficial approach in many circumstances. Frequently however, the physician may know exactly what drug they wish to prescribe, in which case they can [proceed] prescribe via direct drug selection block 67 by proceeding to a direct drug entry screen, and then [specify] specifying the condition targeted by the prescribed treatment when the system prompts entry of the condition block 111.

IN THE CLAIMS:

Claims 1-69 have been cancelled and new claims 70-91 have been added.

46

Select Patient

34

30

32

Name	Age	Gender	Social Security #
Clinton, William	48	Male	222-22-2222
Dougherty, Gracie	60	Female	444-44-4444
Flynn, Grace	20	Female	666-66-6666
Harrington, Mary	49	Female	123-45-6788
Jones, Frederick	36	Male	123-45-6789
Sullivan, Patti	60	Female	111-11-1111

New Pt

OK

Cancel

FIGURE 2

38

39

36

Not a First Line Drug

Cefixime is not the best first line agent available for Otitis Media.
Consider instead:

Amoxicillin

Trimethoprim/Sulfa

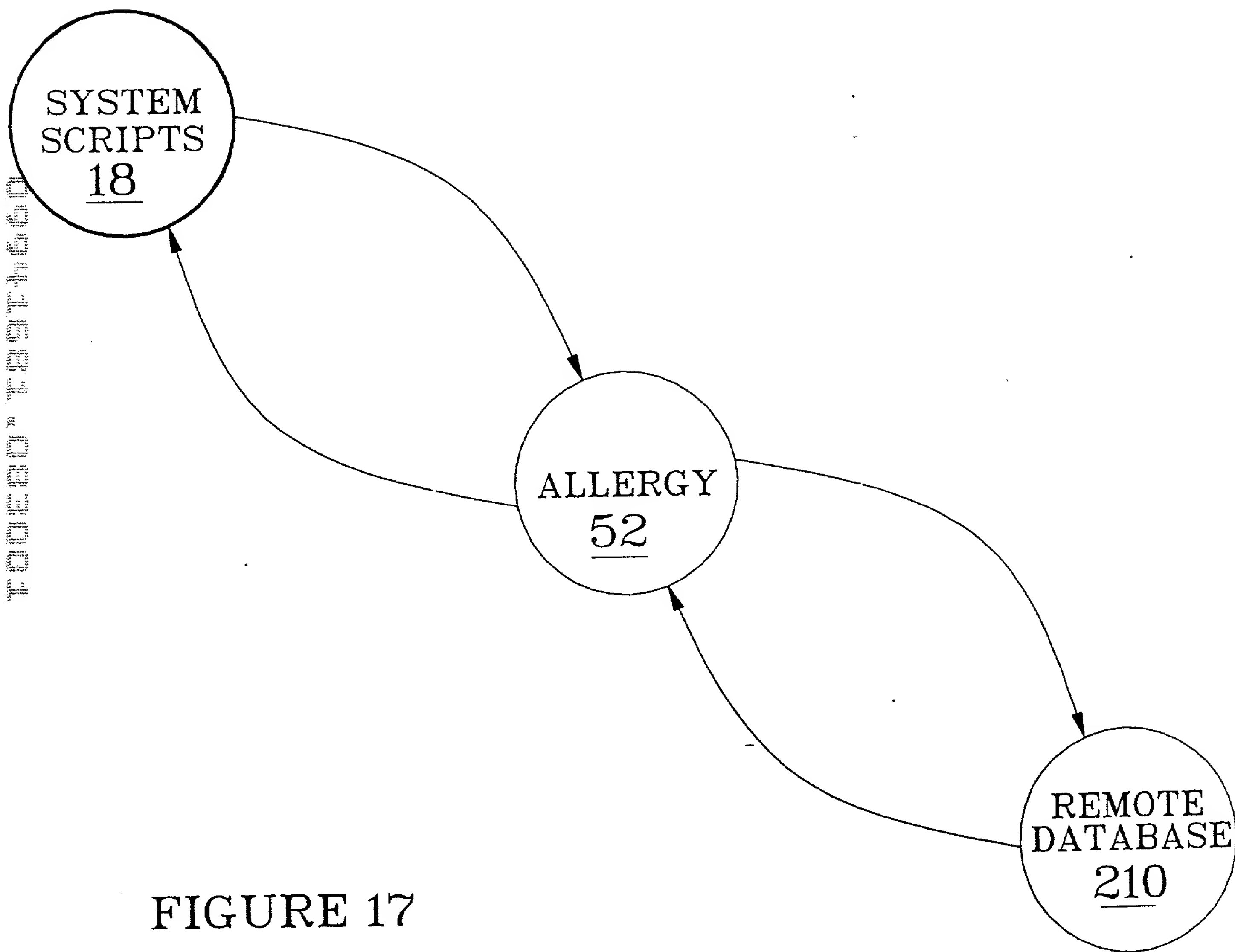
Confirm: *135*

Tx Guidelines

Cefixime

Cancel

FIGURE 11



PROPOSED NEW DRAWING
FIGURE 17

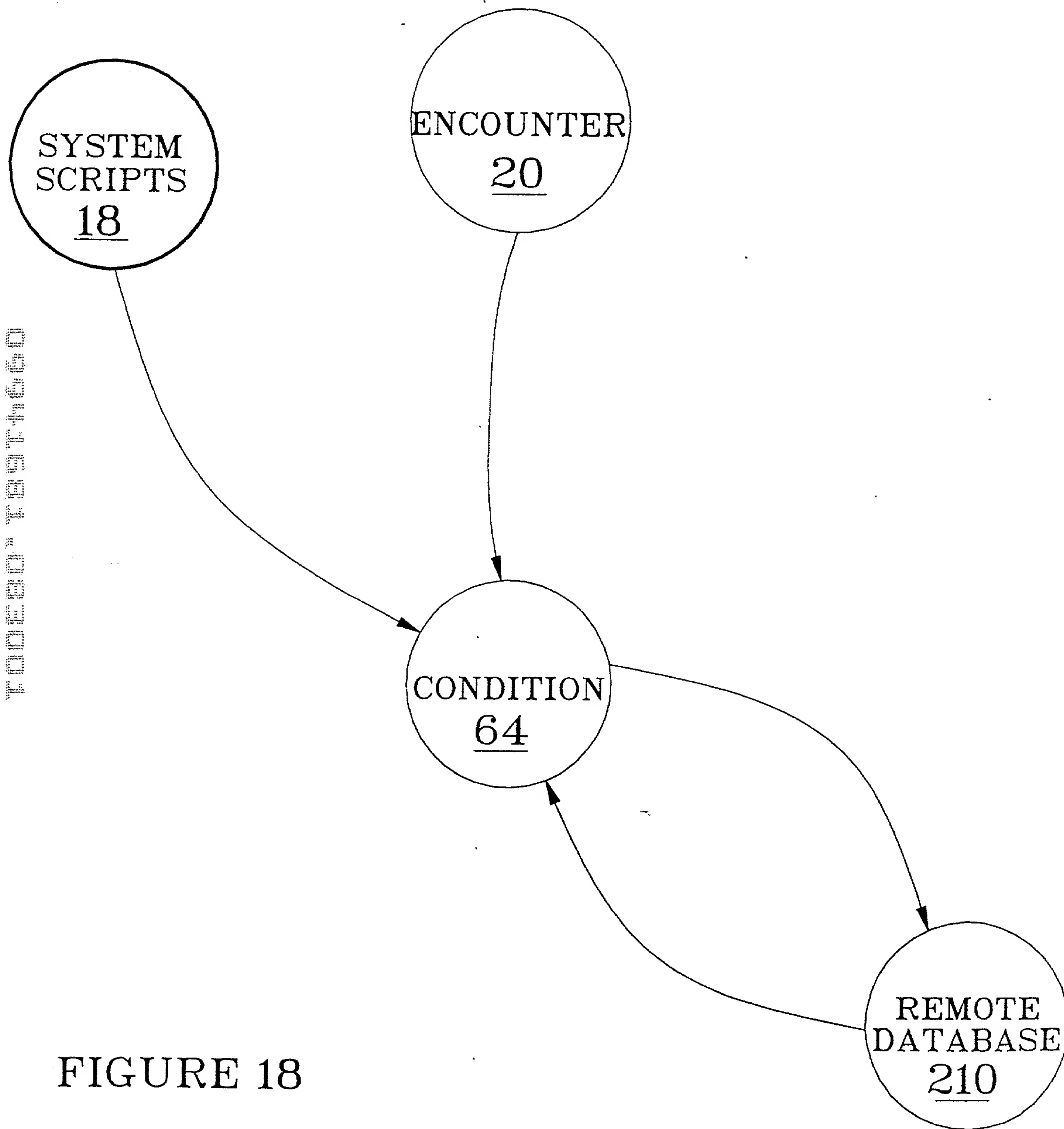


FIGURE 18

PROPOSED NEW DRAWING
FIGURE 18

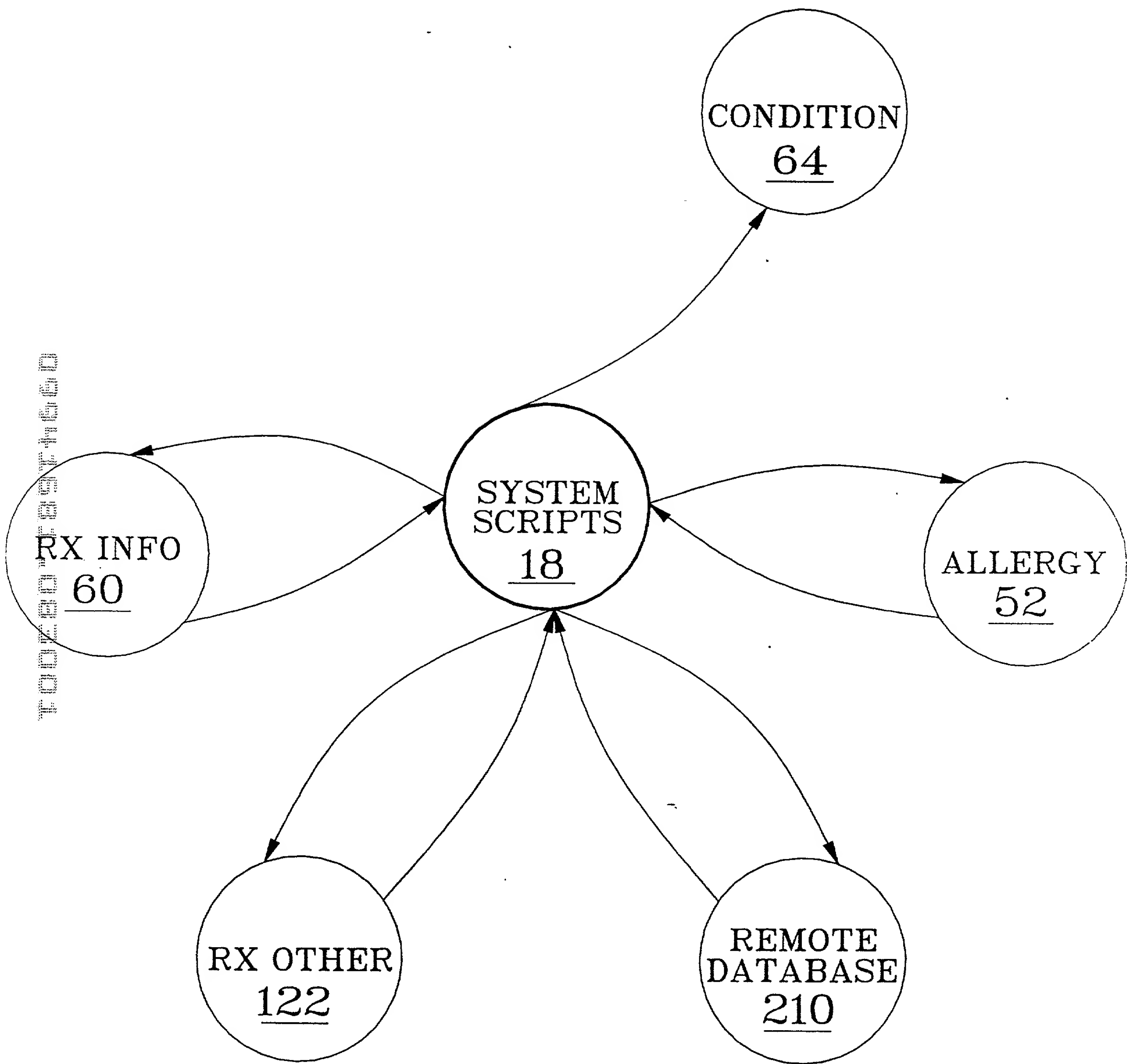


FIGURE 19

PROPOSED NEW DRAWING
FIGURE 19

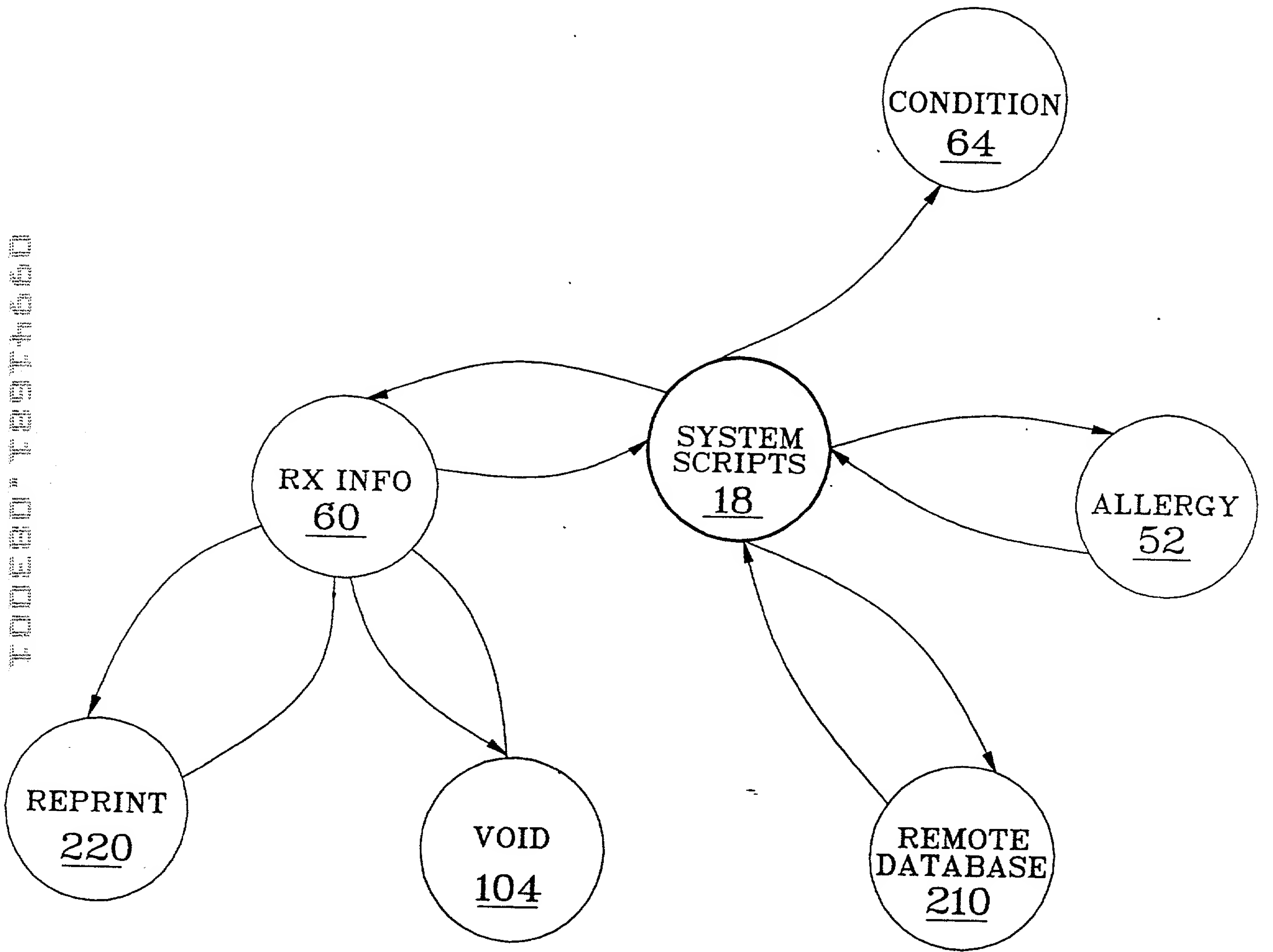


FIGURE 20

PROPOSED NEW DRAWING
FIGURE 20

094161-03001
T00090 T03460

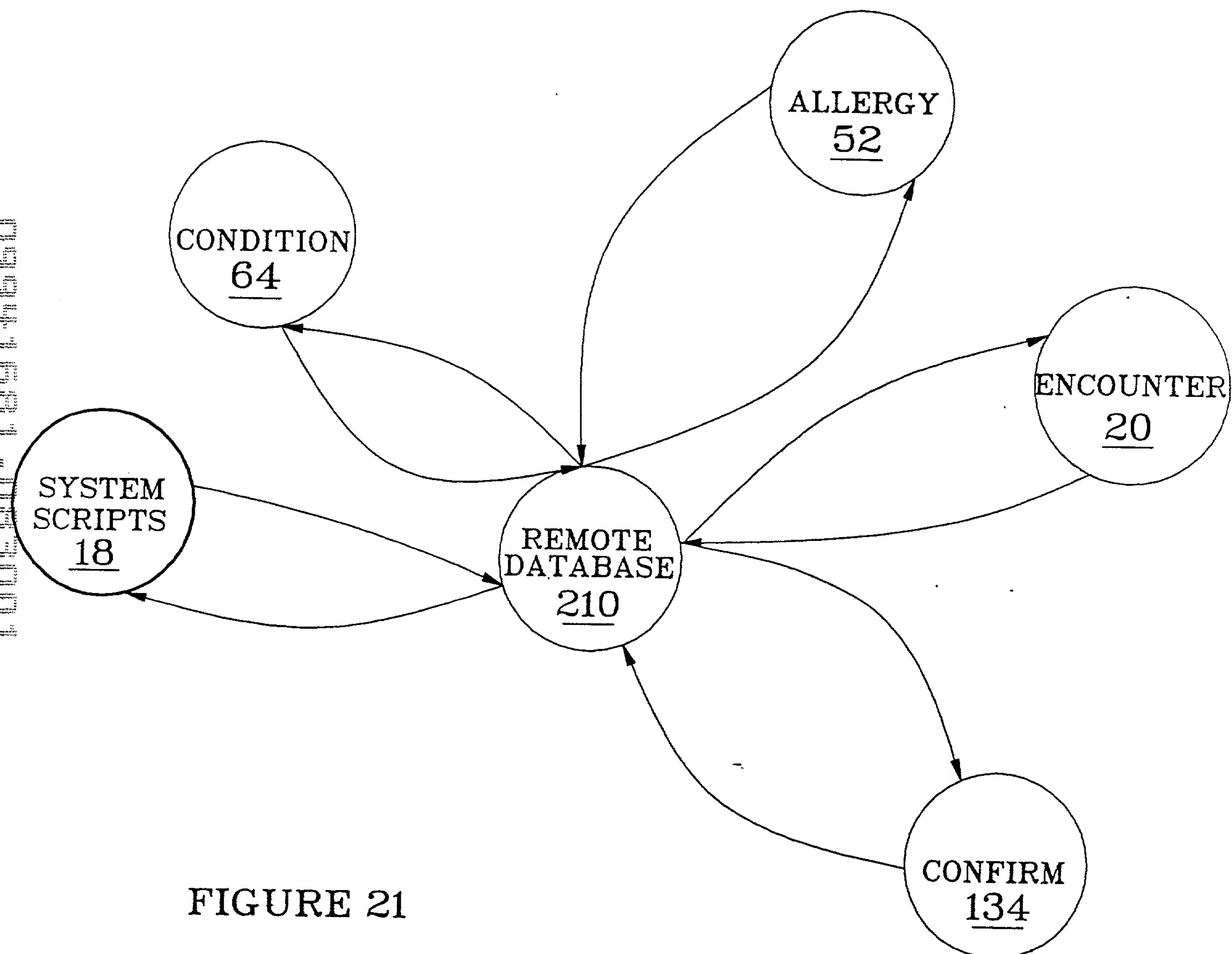


FIGURE 21

PROPOSED NEW DRAWING
FIGURE 21